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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,057	02/05/2001	Colin Brown	331645-1	1282
27162 7590 12/03/2009 CARELLA, BYRNE, BAIN, GILFILLAN, CECCHI, STEWART & OLSTEIN 5 BECKER FARM ROAD ROSELAND, NJ 07068				
EXAMINER WHITE, EVERETT NMN				
ART UNIT		PAPER NUMBER		
1623				
MAIL DATE		DELIVERY MODE		
12/03/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/700,057

**Applicant(s)**

BROWN, COLIN

**Examiner**

EVERETT WHITE

**Art Unit**

1623

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23, 26-35 and 45-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23, 26-35 and 45-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-144a or PTO-854a)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date July 20, 2009

### **DETAILED ACTION**

1. The amendment filed July 13, 2009 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
  - (A) Claims 1-22, 24, 25 and 36-44 were previously canceled;
  - (B) Comments regarding Office Action have been provided drawn to:
    - (I) 103(a) rejection, rendered moot by new ground of rejection over a newly cited reference.
2. Claims 23, 26-35 and 45-83 are pending in the case. It is noticed that in the list of claims filed July 13, 2009, Claim 83 is missing. There is no indication in Applicant's response that Claim 83 has been canceled.

### ***Claim Rejections - 35 USC § 103***

#### ***New Ground of Rejection***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 23, 26-35 and 45-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobbie ("Separation of Peritoneal Surfaces Through the Maintenance of an Artificial Ascites as a Preventative of Peritoneal Adhesions" Abstract, from The 4th Peritoneum and Peritoneal Access Meeting, September 16-19, 1997,

already of record) in view of Milner (US Patent No. 4,886,789, already of record) or Holtz et al (Fertility and Sterility, volume 33, number 6, June 1980, pages 660-662, and volume 34, number 4, October 1980, pages 394-395, newly cited).

Applicant claims a method of reducing the incidence of post-operative adhesions in a body cavity, comprising introducing into the body cavity a composition comprising an aqueous formulation further comprising a polysaccharide dextrin in an amount effective to reduce the incidence of said post-operative adhesions, wherein the dextrin is unsubstituted and the dextrin contains more than 15% of polymers with a degree of polymerization (DP) greater than 12 and acts as an osmotic agent to maintain a volume of the aqueous formulation in the body cavity serving to separate tissues which otherwise may adhere to each other, and wherein the aqueous formulation is a solution in the body cavity and further remains in the body cavity for at least 2 days.

The abstract of the Dobbie reference discloses development of Icodextrin (glucose polymer) as a non-glycating, long-dwell, peritoneal solution of physiological osmolarity for use in peritoneal dialysis as a dialysate, a carrier solution for continuous ambulatory chemotherapy, and for use post-operatively in patients with a high risk of abdominal adhesions. This statement embraces the general description of the instantly claimed method of reducing the incidence of adhesions in a body cavity since the terms Icodextrin and non-glycating; peritoneal & abdominal; post-operatively; and long-dwell all suggest the dextrin, body cavity, unsubstituted dextrin, post-operative and the period of time disclosed in the instant claims.

The instantly claimed method of reducing the incidence of adhesion in a body cavity differs from the separation of peritoneal surfaces described in Dobbie reference by claiming that the dextrin contains more than 15% of polymers with a degree of polymerization (DP) greater than 12.

However, the Milner patent shows that dextrin having 15% polymers with a degree of polymerization greater than 12 is well known in the art. The Milner patent discloses a peritoneal dialysis composition containing an osmotic agent comprising a glucose polymer mixture, said mixture including at least 15% by weight of glucose polymers having a DP greater than 12 (see abstract). See column 6, line 39 and 43,

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wherein preparation of the glucose polymer mixture is described and wherein the term dextrinised starch is mention, which suggest that the glucose polymer mixture of the Milner patent is dextrin. Also see column 9, line 9, wherein the Milner patent describes a typical peritoneal dialysis solution as comprising 2 to 15% w/v of glucose polymer, which falls within the amount of concentrated dextrin that may be applied to a body cavity disclosed in instant Claims 32-34, 65, 75 and 82. See column 11, lines 22-24 wherein the Milner patent describes an infusion of peritoneal dialysis solutions being 2 liters in volume, wherein a total amount of infusion may be 6 liters per day, which embraces the volume of the amount of the composition disclosed in instant Claims 30, 31, 63, 64, 73 and 74.

In the articles appearing in Fertility and Sterility, volume 33, number 6, June 1980, pages 660-662, Holtz et al and volume 34, number 4, October 1980, pages 394-395, by Holtz et al, results are reported of the adhesion reducing effects of a 32% (aqueous) solution of dextran 70 containing 10% dextrose (sold under the trade name HYSKON. The articles show that the inhibition of peritoneal adhesion with 32% dextran 70 was well known in the art at the time of the instant invention. Although dextran 70 is not identical to dextrin, the articles further show that use of glucose containing compounds in post-operative adhesions in the body cavity was known in the art at the time of the instant invention.

One of ordinary skill in this are would be motivated to combine the teachings of the Dobbie reference with the Milner patent or the Holtz et al reference since the references discloses the application of a glucose containing products to the peritoneal cavity or the prevention of postoperative adhesion.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the dextrin used to reduce the incidence of adhesion in a body cavity of the Dobbie reference with dextrin having 15% polymers with a degree of polymerization greater than 12 in view of the recognition in the art, as evidenced by Milner patent, that dextrin having 15% polymers with a degree of polymerization greater than 12 are more effective as osmotic agents than would be indicated by calculation based on the standard assumption that each molecule of such a

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polymer would be osmotically the equivalent of one molecule of dextrose or any other compound.

It also would have been obvious to substitute the Icodextrin used in the general technique of preventing post-operative adhesion of the Dobbie reference for the 32% dextran 70 in dextrose used in the postoperative adhesion prevention procedure described in the Holtz et al reference in view of the recognition in the art, as evidenced by the Holtz et al reference, that the prevention of postoperative adhesions can be accomplished by a single intraperitoneal medication.

5. Applicant's arguments with respect to Claims 23, 26-35 and 45-83 have been considered but are moot in view of the new ground(s) of rejection.

### ***Response to Arguments***

6. Applicant's arguments filed July 13, 2009 have been fully considered but they are not persuasive. The Examiner maintains that the utility disclosed in the Dobbie reference of using the glucose polymer, Icodextrin, as a carrier solution for continuous ambulatory chemotherapy and for use post-operatively in patients with a high risk of abdominal adhesions makes the instantly claimed method of reducing the incidence of post-operative adhesions in a body cavity by introducing into the body cavity a composition comprising a polysaccharide dextrin in an amount effective to reduce the incidence of postoperative adhesions - obvious. When one of ordinary skill in the art considers the Holtz et al references along with the Dobbie reference, the skill practitioner would know how to carry out the procedure of post-surgical adhesion reduction using a glucose containing composition and would know that continuous dialysis is not required.

### ***Summary***

7. All the pending claims (Claims 23, 26-35 and 45-83) are rejected.

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***Examiner's Telephone Number, Fax Number, and Other Information***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Everett White/

Examiner, Art Unit 1623

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623